

**Claims**

1. Use of ghrelin or an analogue thereof for the preparation of a medicament for one or more of

5

treatment and/or prevention of loss of body weight and body fat and/or

prophylaxis or treatment of cachexia, and/or

10

stimulation of appetite and/or

stimulation of food intake and/or

stimulation of weight gain and/or

15

increasing body fat mass

in a gastrectomized individual.

20

2. The use according to claim 1, wherein the ghrelin or analogue thereof is a ghrelin-like compound or a pharmaceutically acceptable salt thereof

wherein the ghrelin-like compound comprises a structure defined by formula I

25

$Z^1 - (X^1)_m - (X^2) - (X^3)_n - Z^2$ , wherein

$Z^1$  is an optionally present protecting group

each  $X^1$  is independently selected from an amino acid, wherein said amino acid is selected from naturally occurring and synthetic amino acids,

30

$X^2$  is any amino acid selected from naturally occurring and synthetic occurring amino acids, said amino acid being modified with a bulky hydrophobic group, preferably an acyl group, or a fatty acid,

35

each  $X^3$  is independently selected from an amino acid, wherein said amino acid is selected from naturally occurring and synthetic amino acids,

wherein one or more of  $X^1$  and  $X^3$  optionally may be modified by a bulky hydrophobic group, preferably an acyl group, or a fatty acid,

$Z^2$  is an optionally present protecting group,

$m$  is an integer in the range of from 1-10

$n$  is 0 or an integer in the range of from 1-35.

3. Use according to any of the preceding claims, wherein  $m$  is an integer in the range of from 1-9, such as of from 1-8, such as of from 1-7, such as of from 1-6, such as of from 1-5, such as of from 1-4, such as of from 1-3, such as of from 1-2, such as 2,

4. Use according to any of the preceding claims, wherein  $X^2$  is selected from the group of modified Ser, modified Cys and modified Lys, such as wherein  $X^2$  is modified Ser.

5. Use according to any of the preceding claims, wherein the ghrelin-like compound is selected from a compound of

formula II  $Z^1 - \text{Gly} - (X^1)_{m-1} - (X^2) - (X^3)_n - Z^2$ ,

formula III  $Z^1 - \text{Gly} - \text{Ser} - (X^2) - (X^3)_n - Z^2$ , and

formula IV  $Z^1 - \text{Gly} - (X^2) - (X^3)_n - Z^2$ .

6. Use according to claim 5, wherein the ghrelin-like compound is having formula III.

7. Use according to any of the preceding claims, wherein  $(X^3)_n$  comprises a sequence selected from one or more of the sequences shown below:

Phe Leu Ser Pro Glu His Gln

Phe Leu Ser Pro Glu His

5

Phe Leu Ser Pro Glu

Phe Leu Ser Pro

10

Phe Leu Ser

Phe Leu

Phe

15

8. Use according to any of the preceding claims, wherein n is an integer in the range of from 1-25, such as of from 1-24, such as from 1-15, such as of from 1-10, such as of from 10-25, such as of from 10-24, such as of from 15-25, such as of from 15-24,

20

9. Use according to any of the preceding claims, wherein  $(X^3)_n$  is selected from one or more of the sequences shown below:

25

Phe Leu Ser Pro Glu His Gln Arg Val Gln Gln Arg Lys Glu Ser Lys Lys Pro Pro  
Ala Lys Leu Gln Pro Arg

Phe Leu Ser Pro Glu His Gln Arg Val Gln Gln Arg Lys Glu Ser Lys Lys Pro Pro  
Ala Lys Leu Gln Pro

30

Phe Leu Ser Pro Glu His Gln Arg Val Gln Gln Arg Lys Glu Ser Lys Lys Pro Pro  
Ala Lys Leu Gln

Phe Leu Ser Pro Glu His Gln Arg Val Gln Gln Arg Lys Glu Ser Lys Lys Pro Pro  
Ala Lys Leu

35

Phe Leu Ser Pro Glu His Gln Arg Val Gln Gln Arg Lys Glu Ser Lys Lys Pro Pro  
Ala Lys

5 Phe Leu Ser Pro Glu His Gln Arg Val Gln Gln Arg Lys Glu Ser Lys Lys Pro Pro  
Ala

Phe Leu Ser Pro Glu His Gln Arg Val Gln Gln Arg Lys Glu Ser Lys Lys Pro Pro

10 Phe Leu Ser Pro Glu His Gln Arg Val Gln Gln Arg Lys Glu Ser Lys Lys Pro

Phe Leu Ser Pro Glu His Gln Arg Val Gln Gln Arg Lys Glu Ser Lys Lys

Phe Leu Ser Pro Glu His Gln Arg Val Gln Gln Arg Lys Glu Ser Lys

15 Phe Leu Ser Pro Glu His Gln Arg Val Gln Gln Arg Lys Glu Ser

Phe Leu Ser Pro Glu His Gln Arg Val Gln Gln Arg Lys Glu

20 Phe Leu Ser Pro Glu His Gln Arg Val Gln Gln Arg Lys

Phe Leu Ser Pro Glu His Gln Arg Val Gln Gln Arg

Phe Leu Ser Pro Glu His Gln Arg Val Gln Gln

25 Phe Leu Ser Pro Glu His Gln Arg Val Gln

Phe Leu Ser Pro Glu His Gln Arg Val

30 Phe Leu Ser Pro Glu His Gln Arg

Phe Leu Ser Pro Glu His Gln

Phe Leu Ser Pro Glu His

35 Phe Leu Ser Pro Glu

Phe Leu Ser Pro

Phe Leu Ser

5

Phe Leu

Phe

10      10. Use according to any of the preceding claims, wherein the acyl group is selected from a C1-C35 acyl group, such as a C1 – C20 acyl group, such as a C1 – C15 acyl group, such as a C6 – C15 acyl group, such as a C6 – C12 acyl group, such as a C8 – C12 acyl group.

15      11. Use according to any of the preceding claims, wherein the acyl group is selected from the group of C7 acyl group, C8 acyl group, C9 acyl group, C10 acyl group, C11 acyl group, and C12 acyl group.

20      12. Use according to any of the preceding claims, wherein the acyl group is selected from the group of C8 acyl group, and C10 acyl group.

25      13. Use according to any of the preceding claims, wherein the acyl group is selected from the group of C7 acyl group, C9 acyl group, and C11 acyl group, such as from the group of C9 acyl group and C11 acyl group.

14. Use according to any of the preceding claims, wherein the medicament comprises a solution of the ghrelin-like compound or a salt thereof.

30      15. Use according to claim 14, wherein the solvent is saline.

16. The use according to any of the preceding claims, wherein the treatment stimulates appetite and prevents malnutrition of the individual.

35      17. The use according to one or more of claims 1-15, wherein the treatment comprises improving the sense of well being and the quality of life in the individual.

18. The use according to any of the preceding claims in combination with another stomach derived factor.

5 19. The use according to claim 18 wherein the stomach derived factor is selected from pacreastatin, gastrin, histamine, resistine, prostaglandins such as prostaglandin E2, intrinsic factor.

10 20. The use according to any of the preceding claims in combination with another body weight and/or body fat inducing factor.

21. The use according to claim 20 wherein said factor is selected from melanin-concentrating hormone (MCH), MCH receptors agonists, especially MCH receptor 1 agonists, neuropeptide Y (NPY), NPY receptor 1 agonists, NPY receptor 5 agonists, 15 and NPY receptor 2 antagonists including peptide YY (PYY) and PYY (3-36), alpha-melanocyte stimulating hormone (alpha-MSH, alpha-melanocortin), melanocortin-3 receptor (MC3R) antagonists, melanocortin-4 receptor (MC4R) antagonists, agouti-related peptide (Agrp), Agrp- agonists, cocaine- and amphetamine-regulated transcript (CART) antagonists, orexin receptor 1 and receptor 2 agonists, growth hormone (GH), GH receptor agonists, insulin-like growth factor-1 (IGF-1) and IGF-1 20 receptor 1 agonists

22. The use according to any of the preceding claims, wherein the medicament is suitable for oral, nasal, transdermal, pulmonal, or parenteral administration.

25

23.. Use according to any of claims 1-22, wherein the medicament is in a formulation for oral administration.

24. Use according to any claims 1-22, wherein the medicament is in a formulation 30 for nasal administration.

25. Use according to any claims 1-22, wherein the medicament is in a formulation for transdermal administration.

26. Use according to any claims 1-22, wherein the medicament is in a formulation for pulmonal administration.

5 27. Use according to any claims 1-22, wherein the medicament is in a formulation for parenteral administration.

10 28. The use according to any of the preceding claims, wherein the active compound is administered in a dose of from about 0.01 µg/kg body weight to 10 mg/kg body weight daily, preferably between 0.1 to 10 µg /kg body weight.

15 29. Use according to any of the preceding claims, wherein the medicament is administered in a concentration equivalent to from 10 ng to 10 mg ghrelin per kg bodyweight.

30. Use according to any of the preceding claims, wherein the medicament is administered prior to or during a meal.

20 31. Use according to any of the preceding claims, wherein the medicament is administered from one to three times daily, each administration being during a meal or at the most within 90 minutes of a meal, such as at the most within 85 minutes of a meal, such as at the most within 80 minutes of a meal, such as at the most within 75 minutes of a meal, such as at the most within 70 minutes of a meal, such as at the most within 65 minutes of a meal, such as at the most within 60 minutes of a meal, such as at the most within 55 minutes of a meal, such as at the most within 50 minutes of a meal, such as at the most 45 minutes prior to a meal, such as at the most 30 minutes prior to a meal, such as at the most 25 minutes prior to a meal, such as at the most 20 minutes prior to a meal, such as at the most 15 minutes prior to a meal, such as at the most 10 minutes prior to a meal, such as at the most 5 minutes prior to a meal.

35 32. Use according to the previous claim, wherein the medicament is administered 3 times daily.

33. A composition comprising ghrelin or an analogue thereof for the treatment of loss of body weight and body fat in a gastrectomized individual.
- 5 34. The composition according to claim 33 for increasing the appetite, the sense of well being, and the quality of life, and decreasing malnutrition in a gastrectomized individual.
- 10 35. The composition according to any of the claims 33 or 34, which comprises a pharmaceutically acceptable carrier or a diluent.
36. The composition according to any of the claims 33 to 36 in unit dosage form, comprising from about 5 to about 250 mg of the ghrelin or an analogue thereof or a pharmaceutically acceptable salt thereof.
- 15 37. The composition according to any of claims 33-36, wherein the ghrelin or analogue thereof comprises one or more of the features of claims 2-31.